

Claims

1. A process for assembling a medical device (110), the medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer, and the process comprising:

creating an irradiation cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant;

forming the mixture into a unitarily and continuously formed portion (108); and

exposing the unitarily and continuously formed portion (108), at least in part, to cross-linking irradiation.

2. The process according to claim 1, wherein the step of forming the portion (108) comprises forming the mixture into a tubular portion (106).

3. The process according to claim 1, wherein the process is carried out with a mixture comprising: a nylon block copolymer including polyether blocks separated by polyamide blocks, about 0.5 to about 5 percent by weight triallyl isocyanurate and 0 percent to about 25 percent by weight nylon.

4. The process according to claim 1, further comprising connecting an inflatable balloon (18) to the unitarily and continuously formed portion (108).

5. The process according to claim 2, wherein the step of forming the portion (108) further comprises forming a portion intended for use as an inflatable balloon (118) unitarily and continuously with the tubular portion (106), and wherein the

exposing step comprises exposing at least one of the tubular portion (106) and the portion intended for use as an inflatable balloon (118) to cross-linking irradiation.

6. The process according to claim 5, further comprising heating and applying pressure to the portion intended for use as an inflatable balloon (118) so as to form an inflatable balloon (118) from that portion.

7. The process according to claim 2, wherein the step of forming the portion (108) further comprises forming an anchor structure (170) unitarily and continuously with the tubular portion (106), and wherein the exposing step comprises exposing at least one of the anchor structure (170) and the tubular portion (106) to cross-linking irradiation.

8. The process according to claim 7, wherein the step of forming an anchor structure (170) comprises forming a malecot (172), a pigtail (174) or a loop (176).

9. The process according to claim 2, wherein the step of forming the portion (108) comprises forming a catheter shaft (111) from the mixture.

10. The process according to claim 7, wherein the step of forming a catheter shaft (111) comprises forming at least first and second unitarily and continuously formed catheter shaft segments (178 and 180), and wherein the exposing step comprises exposing at least one of the first and second catheter shaft segments (178 or 180) to cross-linking irradiation.

11. The process according to claim 10, wherein the exposing step comprises exposing the first and second unitarily and continuously formed catheter shaft segments (178 and 180) to different amounts of cross-linking irradiation.
12. The process according to claim 10, wherein the step of forming a catheter shaft (111) further comprises forming one of the first and second catheter shaft segments (178 or 180) into a catheter tip (184) and the other of the at least first and second catheter segments (178 or 180) into a catheter body (186).
13. The process according to claim 12, wherein the exposing step comprises exposing the catheter body (186) to cross-linking irradiation.
14. The process according to claim 12, wherein the exposing step comprises exposing the catheter tip (184) to cross-linking irradiation.
15. The process according to claim 14, wherein the step of forming a catheter shaft (111) further comprises forming a step or ledge (188) in the catheter tip (184) near a distal end (190) of the catheter tip (184), and wherein the process further comprises introducing a needle (192) into the catheter shaft (111), the needle (192) bearing on it a ring, collar or enlargement (194) engageable with or abuttable against the step or ledge (188) in the catheter tip (184).

16. The process according to claim 1, wherein the step of forming the portion (108) comprises forming the portion (108) into at least first and second unitarily and continuously formed parts (102 and 104), and wherein the exposing step comprises exposing a unitarily and continuously formed transition zone (105) between the first and second parts (102 and 104) to a continuously varying amount of cross-linking irradiation.

17. The process according to claim 16, further comprising placing a shield (196) of varying density between the unitarily and continuously formed portion (108) and a source of cross-linking irradiation, prior to the exposing step.

18. The process according to claim 1, further comprising placing a shield (198) between the unitary and continuously formed portion (108) and a source of cross-linking irradiation, prior to the exposing step.

19. The process according to claim 1, wherein the forming step comprises forming a unitarily and continuously formed portion (108) which extends longitudinally, and wherein said process further comprises placing a shield (196) of varying density between the unitarily and continuously formed portion (108) and a source of cross-linking irradiation.

20. The process according to claim 9, wherein the forming step comprises forming a catheter shaft (111) comprising an outer catheter shaft (114) and an inner

catheter shaft (112) received in the outer catheter shaft (114), the outer catheter shaft (114) comprising the irradiation cross-linkable mixture.

21. The process according to claim 20, further comprising connecting an inflatable balloon (18) to the outer catheter shaft (114) and the inner catheter shaft (112), the inflatable balloon (18) not being unitarily and continuously formed with either the outer catheter shaft (114) or the inner catheter shaft (112).

22. The process according to claim 20, wherein the forming step further comprises unitarily and continuously forming with the outer catheter shaft (114) a portion intended for use as an inflatable balloon (118); and wherein the exposing step is carried out so as to provide different durometers to the outer catheter shaft (114) and the portion intended for use as an inflatable balloon (118), by exposing at least one of the outer catheter shaft (114) and the portion intended for use as an inflatable balloon (118) to cross-linking irradiation.

23. The process according to claim 22, further comprising heating and applying pressure to the portion intended for use as an inflatable balloon (118) so as to form an inflatable balloon (118) from that portion.

24. The process according to claim 1, wherein the forming step is carried out so as to yield a unitarily and continuously formed portion (108) comprising at least first and second parts (102 and 104) unitarily and continuously formed with one

another, and the exposing step comprises exposing at least one of the first and second parts (102 or 104) to cross-linking irradiation.

25. The process according to claim 24, wherein the exposing step further comprises exposing the first and second unitarily and continuously formed parts (102 and 104) of the unitarily and continuously formed portion (108) to different amounts of cross-linking irradiation.

26. The process according to claim 1, carried out with a cross-linking reactant comprising:

(a) a difunctional material selected from the class consisting of diallyl adipate; diallyl carbonate; diallyl maleate; diallyl succinate; diallyl tetrabromophthalate; diethyl diallylmalonate; dimethyl diallylmalonate; and 2,2,6,6-tetrabromobisphenol A diallyl ether;

(b) a trifunctional material selected from the class consisting of 2,5-diallyl-4,5-dimethyl-2-cyclopenten-1-one; diallyl fumarate; diallyl itaconate; 1,3,5-triallyl-2-methoxybenzene; triallyl trimesate (triallyl 1,3,5-benzenetricarboxylate); triallyl trimellitate (triallyl 1,2,4-benzenetricarboxylate); and pentaerythritol triallyl ether;

(c) a tetrafunctional material selected from the class consisting of tetraallyl cis,cis,cis,cis-cyclopentane-1,2,3,4-tetracarboxylate; and N,N,N',N'-tetraallylethylenediamine; or

(d) an aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein.

27. The process according to claim 26, wherein the process is carried out with a mixture comprising about 1 to about 3 percent by weight of the difunctional material; about 0.5 to about 1.5 percent by weight of the trifunctional material or the aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein; or about 0.01 to about 1 percent by weight of the tetrafunctional material.

28. The process according to claim 1, wherein the process is carried out with an amount of the at least one cross-linking reactant sufficient to give the unitarily and continuously formed portion (108) a strength generally about equal to that of a unitarily and continuously formed portion (108) composed of the nylon block copolymer and comparably cross-linked by irradiation, but in the absence of any cross-linking reactant, agent or promoter.

29. The process according to claim 1, wherein the exposing step comprises irradiating the mixture with an electron beam or with ultraviolet, X- or gamma rays.

30. The process according to claim 1, wherein the exposing step is carried out at a total fluence of about 0.5 to about 60 megarads.

31. The process according to claim 1, wherein the mixing of the polyamide elastomer and the at least one additional reactant is carried out by compounding.

32. The process according to claim 2, wherein the tubular portion (106) is formed by extruding the mixture of the polyamide elastomer and the at least one additional reactant.

33. The process according to claim 1, wherein the process is carried out with at least one polyamide elastomer selected from the class consisting of polyester amides, polyether ester amides and polyether amides.

34. The process according to claim 33, wherein the process is carried out with a polyamide elastomer comprising a nylon block copolymer.

35. The process according to claim 34, wherein the process is carried out with a nylon block copolymer including polyether blocks separated by polyamide blocks.

36. The process according to claim 26, wherein the process is carried out with an irradiation cross-linkable mixture of a polyamide elastomer and an aromatic molecule containing at least two ring substituents, each of the ring substituents having labile hydrogens at a benzylic site therein, selected from the class consisting of 1,3,5 triethyl benzene; 1,2,4 triethyl benzene; and 1,3,5 triisopropyl benzene.

37. The process according to claim 39, carried out with a mixture of a polyamide elastomer and about 0.5 percent to about 5 percent by weight of the at

least one additional cross-linking reactant, the cross-linking reactant comprising triallyl cyanurate or triallyl isocyanurate.

38. The process according to claim 37, carried out with a mixture further comprising 0 to about 25 percent by weight nylon.

39. The process according to claim 1, carried out with a mixture of a polyamide elastomer and at least one additional cross-linking reactant, the cross-linking reactant comprising diallyl phthalate or meta-phenylene dimaleimide.

40. The process according to claim 39, wherein the process is carried out with a mixture comprising about 1 to about 3 percent by weight of the at least one cross-linking reactant.

41. A process for assembling a medical device (110), the medical device (110) comprising a unitarily and continuously formed portion (108) having a varying durometer, and the process comprising:

creating an irradiation cross-linkable mixture of a polyamide elastomer and at least one additional cross-linking reactant;

forming the mixture into a unitarily and continuously formed portion (108); and exposing the unitarily and continuously formed portion (108), at least in part, to cross-linking irradiation;

wherein the step of forming the portion (108) comprises forming the mixture into a tubular portion (106);

wherein the forming step is carried out so as to yield a unitarily and continuously formed portion (108) comprising at least first and second parts (102 and 104) unitarily and continuously formed with one another, and the exposing step comprises exposing at least one of the first and second parts (102 or 104) to cross-linking irradiation;

wherein the exposing step comprises irradiating the mixture with an electron beam at a total fluence of about 0.5 to about 60 megarads;

wherein the mixing of the polyamide elastomer and the at least one additional reactant is carried out by compounding, and wherein the tubular portion (106) is formed by extruding the mixture of the polyamide elastomer and the at least one additional reactant; and

wherein the process is carried out with a mixture comprising: a nylon block copolymer including polyether blocks separated by polyamide blocks, about 3 percent by weight triallyl isocyanurate and about 10 percent by weight nylon.